

REMARKS

Claims 41-55 and 163-193 are pending. Claims 1-40 and 56-162 are cancelled, and claims 42-46, 48, 51-55, and 163-193 are withdrawn from consideration. Claims 41, 47, 49, and 50 are under examination and stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This rejection is addressed below.

Amendments to the claims

Claims 41, 44, 45, 48-51, and 163-165 are amended. Claims 41, 44, 45, 48-51, and 163 have been amended to clarify the structure of peptides comprising cyclic amino acid residues, such as Pro and Hyp, and the formulae II and IIa. Support for these changes is found, for example, in previous claim 41 and in peptides such as SEQ ID NO:287, which read on claim 41 and include cyclic amino acid residues such as proline and hydroxyproline. Claim 163 has also been amended to delete the limitation “m=0.” Claims 164 and 165 have been amended to depend from claim 163. These amendments add no new matter.

Restriction of claims

In the action, the Office has withdrawn new claims 163-193 from consideration, alleging that they are drawn to non-elected species. Applicants respectfully note that claim 165 recites the elected species (SEQ ID NO:287) and thus should not be withdrawn from consideration.

Applicants also submit that restriction of claims 48 and 52 is improper, as these claims read on the elected species as well. The elected species, cyclo(-Gly-Ala-Gly-Hyp-Pro-Tyr-Asn-) (SEQ ID NO:287), can be represented by Formula XII as follows:

Formula XII	R _d	R _e	R _f	R _g	R _h	R _i	R _j
Amino acid side chain	Gly	Ala	Gly	Hyp	Pro	Tyr	Asn

Claim 48 recites that R_f can be the amino acid side chain of Ala or Gly, and claim 52 recites that R_i can be the amino acid side chain Tyr, Phe, Trp, or Nal, optionally substituted with one or more of hydroxy, F, or Cl in the aromatic ring. As SEQ ID NO:287 has a glycine side chain as R_f and a tyrosine side chain as R_i, the elected species reads on each of these claims. Applicants therefore request examination of claims 48 and 52.

Finally, applicants note that the elected species reads on claim 163, as amended. Examination of this claim is also respectfully requested.

Written description rejection

The Office has rejected claims 41, 47, 49, and 50 as failing to comply with the written description requirement. As set forth in the M.P.E.P.:

The written description requirement for a claimed genus may be satisfied *through sufficient description of a representative number of species* by actual reduction to practice, reduction to drawings, or *by disclosure of relevant, identifying characteristics, i.e., structure* or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

M.P.E.P. § 2163(II)(A)(3)(ii), emphasis added. The written description requirement for a claimed genus can therefore be met by disclosing a representative number of species along with their structure. As the specification provides the structure of many peptides within the scope of claim 41, including retro, all D, and retro all D compounds, applicants submit that this disclosure satisfies the written description requirement. The rejection on these grounds should be withdrawn.

In making the written description rejection, the Office asserts that there is a single species disclosed that is within the scope of the claimed genus, i.e., SEQ ID NO:287. As

noted in the reply filed September 27, 2007 and described below, this is simply incorrect. The specification provides structures for dozens of compounds within the scope of claim 41. Applicants direct the Office's attention to pages 121-145 of the specification. Here, the structure and synthesis of compounds 2-14, 22-26, 31, 32, and 35-44, which read on claim 41, are described.

The Office also rejects the claims on the basis that "the instant specification gives little to no guidance for the retro form, all D form and retro all D form of the peptide sequence of formula XII." As pointed out in the previous reply, the specification indeed provides structures for a representative number of retro, all D, and retro all D peptides of claim 41.

To explain which retro, all D, and retro all D peptides fall within the scope of claim 41, the general requirements of this claim are summarized as follows. The peptides of claim 41 may be linear, cyclic via N* and C*, or cyclic via C* and R_d. Amino acid residues comprising R_a, R_b, R_c, R_e, R_f, R_h, and R_j are optional (as the value of each of j, k, l, m, n, p, and q is independently 0 or 1). The amino acids containing residues R_d, R_g, and R_i are required by formula XII.

If the peptide is linear, the amino acid containing the side chain R_a, if present, is at the N terminus of the peptide. Otherwise, the amino acid containing R_b, R_c, or R_d forms the N-terminus. Likewise, the amino acid residue containing R_j (or R_i, if R_j is not present) is at the C terminus. A retro amino acid sequence would therefore have the amino acid containing R_j or R_i at the N terminus. Similarly, "all D" peptides have the D form of the amino acids substituted for the L form more commonly found in naturally occurring proteins. The D form peptides can also be in retro form (i.e., where R_j or R_i is the N terminal amino acid side chain). Specific examples of each type of these peptides are described below.

The sequences shown below are written conventionally, from the N terminus to the C terminus. In non-retro sequences, the side chains R_a to R_j run alphabetically, whereas they run in reverse alphabetical order for retro sequences.

As the Office has correctly noted, SEQ ID NO:287 falls within the scope of the claim:

Formula XII	R_d	R_e	R_f	R_g	R_h	R_i	R_j
Amino acid side chain	Gly	Ala	Gly	Hyp	Pro	Tyr	Asn

SEQ ID NO:287 is cyclic peptide cyclized at N^* and C^* . The peptide contains L amino acids and is in non-retro form.

Another example of a peptide described by formula XII is Compound 2. The sequence of this compound can be described as follows.

Formula XII	R_i	R_h	R_g	R_f	R_g	R_d
Amino acid side chain	D-Tyr	D-Pro	D-4-Hyp	Gly	D-Ala	Gly

The synthesis of compound 2 is described on pages 118-119 of the specification. This is a “retro all D” peptide, as the side chain of the N-terminal amino acid is identified by R_i , and the peptides are in the D amino acid form. (Gly is not designated, as it is not chiral.) The “retro” form of this compound (i.e., retro, with L amino acids) is disclosed as SEQ ID NO:71.

Compound 24 is another example of a “retro all D” peptide. This peptide is disclosed in the specification and reads on claim 41.

Formula XII	R_i	R_h	R_g	R_f	R_g	R_d
Amino acid side chain	D-Tyr(3,5-di-I)	D-Pro	D-Hyp	Gly	D-Ala	Gly

The sequence and synthesis of compound 24 is disclosed on page 130 of the specification.

Numerous peptides and their “all D” and “retro all D” forms are disclosed in the application. As a representative sample, the sequences disclosed on page 7 of the patent application publication (page 14, line 20, through page 15, line 10 of the specification) are considered. Of these, SEQ ID NOS:71, 72, 73, 74, 76, 77, 80, 81, 82, and 83 are retro

sequences. The “all D” forms of these sequences are also disclosed in the specification. Therefore, the application clearly discloses a representative number of retro and “retro all D” sequences falling within the scope of claim 41. As a particular example, SEQ ID NO:77 is retro sequence:

Formula XII	R _i	R _h	R _g	R _f	R _g	R _d
Amino acid side chain	Tyr	Pro	Sar	Gly	Ala	Gly

The “retro all D” form of this sequence is disclosed in the application as well (see page 14, line 37, of the specification).

Non retro peptides within the scope of claim 41 are also disclosed; see, e.g., SEQ ID NO:75 at page 14, line 32, of the specification.

Formula XII	R _c	R _d	R _g	R _h	R _i	R _j
Amino acid side chain	Tyr	Sar	4-Hyp	Gly	Ala	Gly

The corresponding, “all D” form of this sequence is disclosed at page 14, line 33, of the specification.

The sequences disclosed on page 7 of the patent application publication are merely taken as representative examples, to show that the application provides a written description of sequences across the scope of claim 41. Numerous other sequences, including retro, “all D,” and “retro all D” sequences reading on claim 41 are also disclosed throughout the specification.

Finally, the Office makes two other points regarding the claimed genus of compounds. First, the Office asserts (page 5 of the action) that the specification provides experimental results from compound 2 (SEQ ID NO:298) only. While the Office is incorrect on this point (see, e.g., Tables 1 and 2), the provided structural information regarding the claimed compounds is nonetheless sufficient to meet the written description requirement.

The Office also states that one can not always expect the same biological activity from two different peptides. Applicants certainly do not dispute that peptides or

compounds with different structures can have different biological activities, as the function of any compound related to its structure. This does not, however, mean that chemical compounds cannot be claimed according to structure. As applicants have shown possession through description of the structures of a representative number of compounds, the genus of compounds of claim 41 are adequately described in the specification, thus satisfying the written description requirement.

For all of these reasons, the written description rejection should be withdrawn.

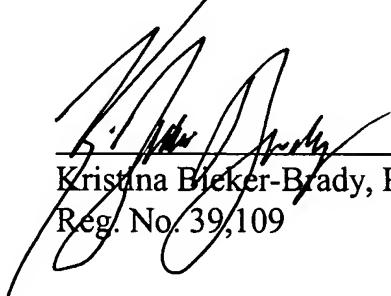
CONCLUSION

Applicants submit that the claims are in condition for allowance and such action is respectfully requested. Enclosed are a Request for Continued Examination and a Petition to extend the period for replying to the final Office action for three (3) months, to and including June 30, 2008. Checks in payment of the required fees are also enclosed.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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